

EXHIBIT 1

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Source: USPQ, 2d Series (1986 - Present) > U.S. Court of Appeals, Federal Circuit > Chen v. Bouchard, 68 USPQ2d 1705 (Fed. Cir. 2003)

**68 USPQ2d 1705
Chen v. Bouchard
U.S. Court of Appeals
Federal Circuit**

No. 03-1037

Decided October 22, 2003

347 F3d 1299

Headnotes**PATENTS****[1] Patentability/Validity — Date of invention — Conception (►115.0403)****Patentability/Validity — Date of invention — Reduction to practice (►115.0405)****Patentability/Validity — Specification — Written description (►115.1103)**

Junior party in interference is not entitled to benefit of priority applications, which misidentified products resulting from methods of synthesis described therein, as proof of prior conception and reduction to practice of chemical invention of counts, despite junior party's assertion that methods described in applications invariably produced compounds of counts, since there was no explicit disclosure of compounds of counts in priority applications, and since it is undisputed that procedures described in applications actually produced products described in applications, namely, certain fluorotaxol derivatives that are not invention involved in interference.

[2] Practice and procedure in Patent and Trademark Office — Interference — Evidence (►110.1709)

Board of Patent Appeals and Interferences did not abuse its discretion by suppressing, as hearsay, notebooks and associated data offered into evidence by junior party, since research assistant who authored notebooks was not called to testify, since board properly concluded that notebooks do not fall within "business records" or "catchall" exceptions to hearsay rule, and since board had authority to choose not to consider hearsay evidence even if senior party did not timely move to suppress.

[3] Patentability/Validity — Date of invention — Conception (►115.0403)**Patentability/Validity — Date of invention — Diligence (►115.0409)**

Analytical chemist need not be "kept in the dark" as to what putative inventor believes analyzed compound's structure is in order for chemist's later testimony to have corroborative value as evidence of conception; issue is not whether analytical chemist knew beforehand what inventor thought he had obtained, but whether chemist actually conducted tests to prove identity of what inventor obtained.

[4] Patentability/Validity — Date of invention — Conception (►115.0403)

Patentability/Validity — Date of invention — Reduction to practice (► 115.0405)**Patentability/Validity — Date of invention — Diligence (► 115.0409)**

Junior party in interference failed to prove that they actually reduced to practice chemical compounds within subject matter of counts prior to senior party's effective filing date, since record does not indicate how, if at all, data obtained by analytical chemists to whom junior party sent its compounds for analysis "confirm" junior party's suggested structures, in that it cannot be determined what formed underlying basis for chemists' belief that tested samples were "consistent" with structures proposed by junior party, and since there is no evidence corroborating junior party's testimony concerning alleged actual reductions to practice; junior party likewise failed to show prior conception coupled with diligence toward reduction to practice, since junior party provided no reliable evidence to support their claim of reasonable diligence during "critical period."

Particular Patents**Particular patents — Chemical — Taxol derivatives**

5,254,580, Chen and Farina, 7,8-cyclopropataxanes, inventors held not entitled to claims corresponding to counts in interference no. 103,675.

Case History and Disposition

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Patent interference (no. 103,675) between Shu-Hui Chen and Vittorio Farina, junior party, and Herve Bouchard, Jean-Dominique Bourzat, and Alain Commerçon, senior party. Junior party appeals from decision awarding

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judgment to senior party. Affirmed; Newman, J., dissenting in part in separate opinion.

Attorneys

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Judge

Before Newman, Lourie, and Schall, circuit judges.

Opinion Text**Opinion By:**

Lourie, J.

Shu-Hui Chen and Vittorio Farina (collectively "Chen") appeal from the decision of the United States Patent and Trademark Office ("PTO") Board of Patent Appeals and Interferences awarding judgment to appellees Hervé Bouchard, Jean-Dominique Bourzat, and Alain Commerçon (collectively "Bouchard"), the senior party, in Interference No. 103,675. *Chen v. Bouchard*, Inter. No. 103,675, Paper No. 336 (Bd. Pat. App. & Interfs. Aug. 2, 2002). Because the Board's decision was supported by substantial evidence and not contrary to law, and its evidentiary rulings do not reflect an abuse of discretion, we affirm.

BACKGROUND

On October 24, 1995, the PTO declared the present interference between Chen's U.S. Patent 5,254,580, assigned to Bristol-Myers Squibb Company, and Bouchard's application U.S.S.N. 08/162,984, assigned to Rhône-Poulenc Rorer S.A. *Id.*, slip op. at 1-2. The Chen patent issued from application U.S.S.N. 08/029,819, filed March 11, 1993, which was a continuation-in-part of application U.S.S.N. 08/006,423, filed January 19, 1993, which was in turn a continuation of application U.S.S.N.

07/907,261, filed July 1, 1992. The Bouchard application was filed December 8, 1993, and was accorded the benefit of the filing date of Bouchard's French application (No. 92 14813), filed December 9, 1992.

Chen's '261 application, entitled "Fluoro Taxols," was directed entirely to taxol derivatives and derivatives of baccatin III (a precursor of taxol) having fluorine in place of taxol's 7-hydroxy group, and described methods purportedly useful for the synthesis of those derivatives by fluorinating taxol derivatives with (diethylamino)sulfur trifluoride ("DAST"). *Id.* at 13-18. The application's claims were directed to those derivatives, pharmaceutical formulations containing them, and methods of using them to treat tumors. *Id.* at 18. The PTO allowed all of the claims in the '261 application in August 1992, just a month after the application was filed, and Chen paid the issue fee in November of that year. *Id.*

On January 19, 1993, Chen filed a petition to withdraw the '261 application from issuance, stating that it had been discovered that the methods described in that application did not produce mixtures of 7 α - and 7 β -fluorotaxols, as had previously been believed, but instead produced mixtures of 7 α -fluorotaxols and 7,8-cyclopropataxols (*i.e.*, taxol derivatives in which taxol's 8-methyl group's carbon has displaced its 7-hydroxy group to form a fused three-membered ring). *Id.* at 18-19. Along with the petition to withdraw, Chen filed the '423 continuation application, pursuant to then-existing 37 C.F.R. §1.60,¹ together with a preliminary amendment that cancelled all the original claims in the continuation application and added claims directed to cyclopropataxol and cyclopropabaccatin III derivatives. *Id.* at 19-20. Chen later filed another preliminary amendment to replace the β -fluorotaxols in the '423 application's drawings with drawings reflecting the cyclopropataxol structures. *Id.* at 20. A short time later, Chen filed the '819 CIP application, entitled "7,8-Cyclopropataxanes," claiming priority from both the '261 and the '423 applications and including a revised specification and claims to 7,8-cyclopropataxols, pharmaceutical formulations containing the same, a treatment method, and 7,8-cyclopropabaccatin III derivatives. *Id.* at 22.

¹ "Rule 60," as 37 C.F.R. §1.60 was commonly known, was repealed on October 10, 1997. See Changes to Patent Practice and Procedure, 62 Fed. Reg. 53,132, 53,188 (1997).

The PTO thereafter rejected all of the new claims in the '423 continuation application under 35 U.S.C. § 112, ¶¶ 1 and 2, objected to the designation of that application as a "continuation," and objected to the second preliminary amendment under 35 U.S.C. §132 as containing new matter. *Id.* at 21. Chen subsequently cancelled the claims in that application

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directed to the cyclopropataxol derivatives and intermediates useful for their synthesis, resulting in almost immediate allowance of the remaining claims, but later abandoned the application in favor of the '819 CIP application. *Id.* The claims of the '819 application were also quickly allowed by the PTO, and the Chen patent issued from it on October 19, 1993. *Id.* at 22.

Like Chen's '819 CIP application, both the Bouchard application at issue in this interference and Bouchard's French priority application are directed to 7,8-cyclopropataxols.

There are three counts presently in this interference: 2, 3A, and 4. Count 2 corresponds to Chen's claims 7-9 and Bouchard's claim 142; Count 3A corresponds to Chen's claims 10-11 and Bouchard's claim 141; and Count 4 corresponds to Chen's claims 1-6 and 8-9 and Bouchard's claim 140. *Id.* at 6-7. Each of the three counts is written in the alternative, or "bifurcated," form. They read as follows:

Count 2

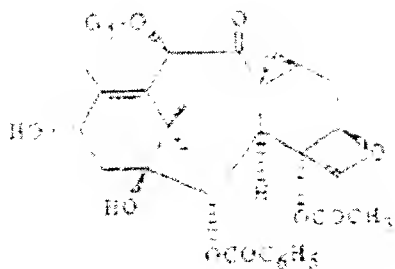
4 α -10 β -diacetoxo-2 α -benzoyloxy-5 β ,20-epoxy-1 β -hydroxy-7 β ,8 β -methylene-9-oxo-19-nor-11-taxen-13 α -yl(2R,3S)-3-tert-butoxycarbonyl-amino-2-hydroxy-3-phenylpropionate

OR

N-debenzoyl-N-t-butoxycarbonyl-7-deoxy-8-desmethyl-7,8-cyclopropataxol.

Count 3A

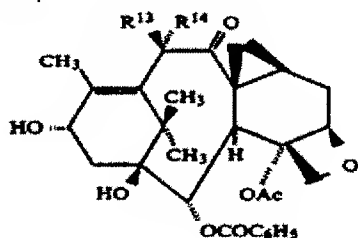
A taxoid of the formula:



in which G_1 represents hydrogen or acetyl,

OR

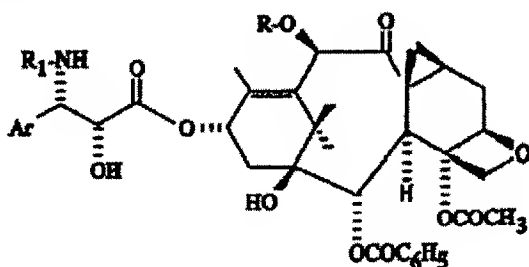
A compound of the formula:



in which R^{13} is hydrogen, acetyloxy or hydroxy; R^{14} is hydrogen; or R^{13} and R^{14} jointly form a carbonyl group.

Count 4

A taxoid of the formula:



in which

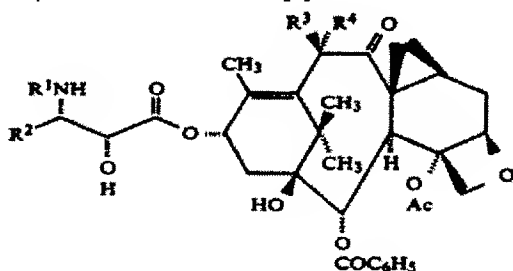
R represents hydrogen or acetyl,

R_1 represents benzoyl or R_2 -O-CO- in which R_2 represents t-butyl, and

Ar represents phenyl or o- or β -naphthyl, said phenyl or naphthyl being unsubstituted or substituted by C_{1-4} alkyl, C_{1-4} -alkoxy, halogen, or CF_3 , or Ar represents 2- or 3-thienyl or 2- or 3-furyl, said thienyl or furyl being unsubstituted or substituted by halogen,

OR

A compound of the formula[:]



in which

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R¹ is -COR² in which R² is t-butyloxy, C₁₋₄ alkyl, C₂₋₆ alkenyl, C₂₋₆ alkynyl, C₃₋₆ cycloalkyl or phenyl, optionally substituted with one to three same or different C₁₋₆ alkyl, C₁₋₆ alkoxy, halogen or -CF₃ groups;

R² is C₁₋₆ alkyl, C₁₋₆ alkenyl, C₂₋₆ alkynyl, C₃₋₆ cycloalkyl, or a radical of the formula -W-R^x in which W is a bond, C₂₋₆ alkenediyl, or -(CH₂)_t-, in which t is one to six; and R^x is naphthyl, furyl, thienyl or phenyl, and furthermore R^x can be optionally substituted with one to three same or different C₁₋₆ alkyl, C₁₋₆ alkoxy, halogen or -CF₃ groups; and

R³ is OCOR, -OCOOR, H, or OH; R⁴ is hydrogen; or R³ and R⁴ jointly form a carbonyl group; and R is C₁₋₆ alkyl.

Both parties filed a number of motions over the course of the interference proceedings, most of which were denied or held to be moot by the Board in its very thorough opinion. *See id.* at 7-8, 35-48. The Board also chastised both parties for failing to state the legal theories on which they relied and for failing to specifically point out the location of the facts, if any, in the record that support the conclusory statements made by the parties. *Id.* at 10. Of primary importance, however, is the Board's denial of Chen's motion for the benefit of his '261 and '423 applications, making Chen the junior party and Bouchard the senior party. The Board held that Chen's earlier applications did not satisfy the written description requirement for any embodiment within the counts. *Id.* at 25-26. The Board rejected Chen's argument that the cyclopropataxols of the count were inherently described by virtue of the fact that the methods described in the examples inevitably result in those compounds. *Id.* at 26-28, 32. The Board also distinguished various prior decisions cited by Chen, based on its reading of those cases as requiring submission of evidence supporting the proposed changes during prosecution, as well as evidence that the error would have been immediately recognized or readily discoverable by a person of ordinary skill in the art. *Id.* at 28-29, 32-33. The Board found that Chen provided no evidence of the discovery of his error prior to Bouchard's effective filing date, and that Chen had used a well-known fluorinating agent that one of ordinary skill would not have predicted would have resulted in cyclopropanation. *Id.* at 29.

The Board also granted Bouchard's motion to suppress as inadmissible hearsay the notebooks of a non-testifying witness and associated data proffered by Chen. *Id.* at 49-58. The Board rejected Chen's arguments that that evidence fell within either the "business records" exception (*i.e.*, Fed. R. Evid. 803(6)) or the "catchall" exception (*i.e.*, Fed. R. Evid. 807) to the hearsay rule, *id.* at 51-56, or that, although certain evidence may be hearsay, Bouchard waived any objections to the evidence by failing to follow the proper procedure for preserving his right to move to suppress that evidence, *id.* at 56-57.

Finally, the Board found that Chen's evidence of reduction to practice, or even conception, prior to the critical date was devoid of corroboration, *id.* at 72-80, and that Chen had failed to provide any corroborated evidence of diligence from just prior to the critical date until reduction to practice, *id.* at 80-109. The Board thus concluded that Chen, as the presumptively junior party in this interference, had failed to meet his burden of demonstrating by a preponderance of the evidence either (1) that he actually reduced to practice the subject matter of the counts before Bouchard's effective filing date, or (2) that he conceived the invention before Bouchard's effective filing date and worked with reasonable diligence up to a constructive or actual reduction to practice. The Board then granted judgment in favor of Bouchard.

Chen now appeals. We have jurisdiction pursuant to 35 U.S.C. §141 and 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

A. Entitlement to Priority

Whether a specification supports a claim corresponding to a count, and thus satisfies the written description requirement of 35 U.S.C. §112, ¶ 1, is a question of fact, *Vas-Cath v. Mahurkar*, 935 F.2d 1555, 1562 [19 USPQ2d 1111] (Fed. Cir. 1991), and is, in appeals from the PTO, reviewed under the substantial evidence standard, *see In re Gartside*, 203 F.3d 1305, 1315 [53 USPQ2d 1769] (Fed. Cir. 2000) (holding that we review factual determinations underlying a legal conclusion that an invention is

obvious under 35 U.S.C. §103 using the substantial evidence standard).

Chen argues that the Board erred in concluding that he was not entitled to the benefit

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of the '261 and '423 applications as proof of his earlier conception and reduction to practice of the invention of the counts. Chen asserts that, although the '261 and '423 applications misidentified the resulting products, the methods described in those applications invariably produced compounds of the counts and therefore demonstrate his constructive reduction to practice. According to Chen, the case law makes it clear that it is the product, not the formula or the name, that is the invention. There is no basis in the law, Chen argues, for requiring a patentee to prove that an error in a specification would have been apparent merely upon reading the specification at the time it was filed in order for the patentee to rely on that specification for proof of reduction to practice. Because, according to Chen, the products inherently had the structures called for by the count, it should not matter what the inventors initially thought the structures were or when the error was discovered, for there is no authority for requiring proof of inherency before grant.

Bouchard responds that the Board's decision was supported by substantial evidence: Chen did not describe any compounds of the counts in the '261 and '423 applications, and, for a party to be entitled to the benefit of an earlier application as a constructive reduction to practice of a count, the earlier disclosure must both describe the invention and enable one of ordinary skill in the art to make it; the '261 and '423 applications did not disclose by name, structure, or analytical characteristics any cyclopropataxol compound. Moreover, Bouchard argues, regardless whether the methods of the '261 application do inherently result in the production of cyclopropataxols, the nuclear magnetic resonance ("NMR") and mass spectrometry ("MS") data reported in that application correspond only to fluorotaxols and are inconsistent with cyclopropataxols; Chen later deleted those very data and added other data, corresponding to the cyclopropataxols, when he filed the '984 CIP application. According to Bouchard, Chen cannot possibly have "described" an invention in the '261 application that he had yet to conceive and in fact excluded from the application. Bouchard also contends that the prior cases cited by Chen are all inapposite, because none of those cases involved an earlier-filed application that described an invention of compounds distinctly different from those later claimed. Rather, in each of the cited cases, the compound or product in question was conceived and essentially disclosed in one way or another at the time the application was filed.

[1] We agree with Bouchard that the Board's decision denying Chen the benefit of his '261 and '423 applications was supported by substantial evidence. Not only did the Board find that there was no explicit disclosure of the compounds of the counts in Chen's priority applications, but it is also undisputed that the procedures described in those applications actually *did* produce some of the products actually described in the applications, namely the 7 α -fluorotaxol derivatives, which are not the invention involved in this appeal.

We also agree with Bouchard that the present case is readily distinguishable from all of the cases relied on by Chen. For example, in *In re Nathan*, 328 F.2d 1005 [140 USPQ 601] (CCPA 1964), the Board had affirmed a new matter rejection raised when the appellants sought to amend their specification and claims to indicate the steric orientation of the 2-halo groups in the claimed 2-halo steroids following a rejection for indefiniteness. In reversing the Board's decision, the court held that "the amendatory material ... is concerned with an inherent characteristic of an illustrative product of appellants' invention already sufficiently identified in appellants' original disclosure as filed." *Id.* at 1009. Unlike in the present case, there was no incorrect structure disclosed in Nathan's originally filed application, but rather a structural formula lacking in a single detail. In that case, moreover, there was a disclosure of a definite melting point range, optical rotation, ultraviolet spectral analysis, and chemical analysis for the product having the orientation that the appellant sought to add to the claim. The Board found no analogous disclosure in Chen's '261 and '423 applications.

In both *In re Magerlein*, 346 F.2d 609 [145 USPQ 683] (CCPA 1965), and *Spero v. Ringold*, 377 F.2d 652 [153 USPQ 726] (CCPA 1967), as in *Nathan*, the court found that the structures of the claimed compounds were correctly disclosed in the corresponding applications, the only deficiency being that the compounds' steric configurations were not specifically stated. *Magerlein*, 346 F.2d at 612; *Spero*, 377 F.2d at 656.

In *Ex Parte Marsili*, 214 USPQ 904 (Bd. Pat. App. & Interfs. 1979), a holding not binding

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on this court, the applicants initially disclosed that they had prepared compounds containing an

imidazoline (also called a "dihydro-imidazole") ring, when in fact the described methods produced compounds having more stable, aromatic imidazole rings. In reversing a new matter rejection raised after the applicant sought to correct the structure in claim 1 of the patent application, the Board found that the question was not one of "adding characteristics not previously mentioned," but rather of "changing the original description of a product which ... was described by sufficient characteristics to distinguish it." *Id.* at 905. The Board accordingly found that "the products described, exemplified and claimed by Appellants inherently had and have now the structure given in the amendment in question," and held that "the changes made in this amendment do not constitute new matter." *Id.* at 906. The '261 and '423 applications, in contrast, not only do not disclose the structural formulae of any cyclopropataxol derivatives, they apparently also do not disclose any analytical data or other characteristics of such derivatives.

In *Reister v. Kendall*, 159 F.2d 732 (CCPA 1947), the court affirmed a Board decision that a party to an interference was entitled to a prior filing date even though it had disclosed an erroneous structural formula for a claimed dye, where the asserted priority application sufficiently disclosed the subject matter of the counts even in view of the error. The Board had found in that case that the priority application "disclosed not only the complete process for preparing the dyestuffs but also the dyestuffs themselves and the means for identifying them that are called for by the counts." *Id.* at 733. In contrast, neither any cyclopropataxols nor any analytical data corresponding to cyclopropataxols were disclosed in Chen's earlier applications.

In *Petisi v. Rennhard*, 363 F.2d 903 [150 USPQ 669] (CCPA 1966), our predecessor court observed that "[t]he product, not the formula or name, is the invention." Likewise, in *Regents of the University of New Mexico v. Knight*, 321 F.3d 1111 [66 USPQ2d 1001] (Fed. Cir. 2003), in the context of a case in which a district court had found that no new matter was added in an amendment correcting a structural formula because there was sufficient evidence to show that the added structure was an inherent and more accurate description of the *disclosed* subject matter, we recently wrote that "a chemical structure is simply a means of describing a compound; it is not the invention itself." *Id.* at 1122. Here, however, Chen did not simply misname or incorrectly illustrate the structural formula of the products that he later asserted were inherently produced; he also failed to disclose any characteristics of those products that would evidence possession of the invention. Indeed, others apparently of skill in the art even confirmed Chen's "identification" of the products as fluorotaxols, demonstrating that it was far from apparent that an error had been made, let alone that Chen had produced cyclopropataxol derivatives within the scope of the counts. The fact that that result was "surprising" was further evidenced by Chen's later publication of an article entitled " *Serendipitous Synthesis of a Cyclopropane-Containing Taxol*" (emphasis added).

The evidence here is overwhelmingly one-sided. The Board found that neither of Chen's asserted priority applications literally "describes," in the sense of the patent statute, any compound within the scope of the counts in this interference. Rather, those applications describe obtaining only 7 α - and 7 β -fluorotaxols and mixtures thereof, not 7,8-cyclopropataxols, and especially not 7,8-cyclopropataxols within any of the counts. *Chen*, slip op. at 25-26. The Board found, furthermore, that, at the time the '261 application was filed, the disclosure therein would have reasonably conveyed to one of skill in the art that fluorination of taxol with DAST, a known fluorination reagent, would have reasonably been expected from Chen's disclosure and from the knowledge possessed by an ordinarily skilled organic chemist at that time. *Id.* at 29-30. In fact, Chen's witness Dr. Kingston testified that the described reaction would have been expected to yield a 7-fluorotaxol at that time. The Board also found that, in contrast, there was no evidence that established that a person of ordinary skill in the art, reading the '261 application at the time it was filed, would have readily understood that instead of obtaining mixtures of 7-fluorotaxol, mixtures of 7-fluorotaxol and 7,8-cyclopropataxols would have resulted by performing the steps set forth in the examples. *Id.* at 33.

Indeed, Dr. Kadow, the Bristol-Myers Squibb researcher who repeated the examples

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of the '261 application in 1996 in order to demonstrate that those examples actually produced cyclopropataxols, testified that Chen would have reasonably interpreted the NMR spectrum for the compound that he produced to be a one-to-one mixture of α - and β -epimers of 7-fluorotaxol, and that it was "reasonable" for Chen to have concluded that the NMR spectrum was consistent with a mixture of fluorotaxols. *Id.* at 30-31. It was against the backdrop of that evidence that the Board found that Chen's applications "would not have been recognized by a person of ordinary skill in the art at the time they were filed as 'describing' (in the sense of the statute) the compounds allegedly discovered by Chen et al. after they filed their applications." *Id.* at 31. Because that finding is supported by

substantial evidence, we affirm the Board's conclusion that Chen's claims to the subject matter of the counts are not entitled to the benefit of the '261 and '423 applications' filing dates.

B. Hearsay

We review evidentiary rulings under an abuse of discretion standard. *Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1547 [31 USPQ2d 1746] (Fed. Cir. 1994). Thus, we will not disturb the Board's evidentiary rulings unless the Board's decision (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact findings; or (4) follows from a record that contains no evidence on which the Board could rationally base its decision. *Gerritsen v. Shirai*, 979 F.2d 1524, 1529 [24 USPQ2d 1912] (Fed. Cir. 1992).

Chen argues that the Board erred by suppressing Jianmei Wei's notebooks and associated data, and additionally that Bouchard did not timely object to the excluded evidence. Moreover, according to Chen, the suppression of evidence was unreasonable, because, Chen asserts, the suppressed exhibits had been authenticated, and the Board suppressed an overly broad swath of testimony.

Bouchard responds that the Board's decision to suppress the evidence was justified: Chen chose not to call Dr. Wei as a witness despite her availability, and the Board has discretion to suppress evidence on its own volition.

[2] We agree with Bouchard that Chen has failed to demonstrate that the Board abused its discretion in its evidentiary rulings. The Board took particular note of the fact that Wei, the author of the notebooks, was not called to testify. The Board also properly concluded, on the basis of its quite thorough analysis, that Wei's notebooks do not fall within the "business records" exception ² or the "catchall" exception ³ to the hearsay rule. Moreover, regardless whether Bouchard failed to timely move to suppress certain evidence, the Board has authority under 37 C.F.R. §1.655(a) to choose not to consider hearsay evidence. While notebook records are obviously of prime importance in proving the elements of invention, the failure of the notebooks' alleged author to testify; the fact that it was not established on the record that those notebooks were actually the notebooks of Wei, except by the circular testimony of Chen, whose activity was what was intended to be corroborated by the notebooks; and the lack of evidence of Bristol-Myers Squibb's policies regarding maintenance of laboratory notebooks, all compel affirmance of the Board's decision to exclude the notebooks, under our abuse of discretion

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standard. We therefore affirm the Board's evidentiary rulings.

² The so-called "business records" exception to the hearsay rule, Fed. R. Evid. 803(6), at all times relevant to this interference, read as follows:

The following are not excluded by the hearsay rule, even though the declarant is available as a witness: ...

(6) Records of regularly conducted activity. A memorandum, report, record, or data compilation, in any form, of acts, events, conditions, opinions, or diagnoses, made at or near the time by, or from information transmitted by, a person with knowledge, if kept in the course of a regularly conducted business activity, and if it was the regular practice of that business activity to make the memorandum, report, record or data compilation, all as shown by the testimony of the custodian or other qualified witness, unless the source of information or the method or circumstances of preparation indicate lack of trustworthiness.

Because Chen presented no testimony from the "custodian or other qualified witness" that Wei's notebooks were "records of regularly conducted activity," relying instead only on Chen's uncorroborated testimony, the Board properly concluded that those notebooks did not fall within the purview of the exception.

³ In relevant part, the "catch-all" exception, Fed. R. Evid. 807, reads as follows:

A statement not specifically covered by Rule 803 or 804 but having equivalent circumstantial guarantees of trustworthiness, is not excluded by the hearsay rule

Because the Board found that Chen offered no evidence of the "circumstantial guarantees of trustworthiness" other than the very documents of Wei that Bouchard sought to exclude, the Board properly concluded that those documents also do not fall within this exception.

C. Reduction to Practice or Conception Plus Diligence

For Chen to prevail in this interference as the junior party, he would have had to have established by a preponderance of the evidence either that he actually reduced to practice the subject matter of the counts before Bouchard's effective filing date or that he had conceived the subject matter of the counts before Bouchard's effective filing date, and followed up with reasonable diligence from just prior to Bouchard's effective filing date up to his own constructive or actual reduction to practice.

Chen contends that the Board erred in concluding that he did not meet his burden of showing that he had conceived any compounds within the counts prior to the critical date. According to Chen, evidence was adduced showing that BMS-183582 and BMS-183821, which were recognized from the start to be cyclopropataxols of Counts 3A and 4, were actually reduced to practice from "7-epi" starting materials before the critical date, even though those syntheses were first disclosed in the '819 application. Chen argues that the identity of those compounds was confirmed by NMR, MS, and x-ray crystallographic analysis by non-inventors prior to the critical date, and that the Board applied an incorrect legal standard of corroboration in making its determination that Chen failed to prove actual reduction to practice. Chen contends that confirmation tests need not be definitive; reasonable certainty is the standard. According to Chen, the Board also erred by holding that structure-confirmation tests by non-inventors are disqualified from serving as corroborating evidence if, as here, the inventor told the non-inventors what he thought the test would show.

Bouchard responds that Chen has provided no corroborating evidence of conception or diligence in reduction to practice. According to Bouchard, cyclopropataxols were unexpected reaction products with a high potential for misidentification during analysis. Bouchard also contends that NMR and MS are unreliable for identifying previously unknown complex molecules, especially when those compounds are in mixtures, and no non-inventor witnesses contemporaneously interpreted the key spectra relied on by Chen. Bouchard points out that Chen's witness Qi Gao, a Senior Research Investigator at Bristol-Myers Squibb, testified that she solved the crystal structure of a cyclopropataxol given to her by Chen prior to the critical date, but did not explain how the x-ray data were obtained or how they demonstrate a cyclopropataxol structure. Like NMR spectra, x-ray diffraction data are capable of multiple interpretations and are not self-proving, according to Bouchard.

It is well established that when a party seeks to prove conception via the oral testimony of a putative inventor, the party must proffer evidence corroborating that testimony. See *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 [38 USPQ2d 1288] (Fed. Cir. 1996); *Price v. Symsek*, 988 F.2d 1187, 1194 [26 USPQ2d 1031] (Fed. Cir. 1993). That rule addresses the concern that a party claiming inventorship might be tempted to describe his actions in an unjustifiably self-serving manner in order to obtain a patent or to maintain an existing patent. See *Eibel Process Co. v. Minn. & Ont. Paper Co.*, 261 U.S. 45, 60 (1923); *Kridl v. McCormick*, 105 F.3d 1446, 1450 [41 USPQ2d 1686] (Fed. Cir. 1997) ("The tribunal must also bear in mind the purpose of corroboration, which is to prevent fraud, by providing independent confirmation of the inventor's testimony."); *Price*, 988 F.2d at 1194-95. There is no particular formula that an inventor must follow in providing corroboration of his testimony of conception. See *Kridl*, 105 F.3d at 1450. Rather, whether a putative inventor's testimony has been sufficiently corroborated is determined by a "rule of reason" analysis, in which "an evaluation of all pertinent evidence must be made so that a sound determination of the credibility of the inventor's story may be reached." *Price*, 988 F.2d at 1195. However, that "rule of reason" analysis does not alter the requirement of corroboration of an inventor's testimony. *Brown v. Barbacid*, 276 F.3d 1327, 1335 [61 USPQ2d 1236] (Fed. Cir. 2002). Evidence of the inventive facts must not rest alone on the testimony of the inventor himself. *Cooper v. Goldfarb*, 154 F.3d 1321, 1330 [47 USPQ2d 1896] (Fed. Cir. 1998).

As an initial matter, we agree with Chen that the Board erred by setting forth an incorrect standard for evaluating corroborating evidence. The Board stated that

Chen et al.'s evidence does establish that samples of compounds prepared by Dr. Chen were forwarded to the analytical section of Bristol-Myers Squibb's laboratory in Wallington, Connecticut, by Dr. Chen for analysis. But in each instance Dr. Chen provided the analytical section with a structural formula of the compound *he* believed he had prepared.

Dr. Chen did not give the analytical section an unknown sample and request a determination of its structure by the analytical section. Thus, the analytical section's alleged "confirmation" of the structure provided to them by Chen *cannot* establish, independently of Dr. Chen's proposed formula, what was the identity of the compound produced because *Dr. Chen* provided them with the structure *he* believed the compound possessed in advance. *Frilette v. Kimberlin*, 412 F.2d 1390, 1398, 162 USPQ 148, 155 (CCPA 1969).

Chen, slip op. at 74-75. The Board further stated that

Ms. Huang's conclusion that the spectra she obtained were "consistent" with Dr. Chen's proposed structure and Dr. Kingston's after the fact conclusion that the spectra obtained were "consistent" with Dr. Chen's proposed structure are not independent analysis or even knowledge independent of Dr. Chen because each relied on Dr. Chen's proposed structure for purposes of their analysis. *Frilette v. Kimberlin*, *supra*.

Id. at 97-98. Finally, the Board noted that,

rather than analyze the samples Dr. Chen gave to the analytical group to determine without the benefit of any prior suggestion of what the compound tested actually was, the analytical group was merely running NMR analyses on the samples and reviewing the samples for evidence that Dr. Chen's proposed structure for the compounds was "consistent" with the NMR spectra.

Id. at 108.

[3] To the extent that the Board's statements quoted above suggest that an analytical chemist must be "kept in the dark" as to what an inventor believes a submitted compound's structure is in order for that chemist's later testimony to have corroborative value, the Board is mistaken. Neither the *Frilette* decision cited by the Board nor any other decision of this court or our predecessor courts requires as much. In the relevant part of *Frilette*, that decision simply held that:

[T]he designation of the material involved in the ... tests in [appellant's witness] Lago's records as "Linde Molecular Sieve 13X calcined ammonium exchange" cannot establish identification since that designation was merely copied by Lago from the label on the bottle in which the sample was given to him by Frilette and was not based on either knowledge or analysis by Lago.

412 F.2d at 1398. The dispositive fact in that case, as we understand it, was not that Lago obtained the molecular sieves from a labeled bottle, but rather that Lago's *only* information regarding the material was the writing on the label that was apparently affixed to the bottle by Frilette, the very person whose statements required corroboration by Lago. There is no suggestion in that decision that Lago's records would not have been adequate to establish identification if Lago had actually analyzed the material or otherwise confirmed its identity, irrespective of whether the bottle was labeled. Thus, the question here is not whether the analytical chemist knew beforehand what Chen thought he had obtained, but whether the chemist herself conducted tests to prove the identity of what Chen obtained.

[4] Nonetheless, the Board's error here was harmless in any event because Chen failed to prove his case. Chen alleged before the Board that he actually reduced to practice six compounds within the counts prior to December 9, 1992. *Chen*, slip op. at 59. The Board found, however, that Chen "utterly failed to explain in his brief how the evidence on which he relies as evidence of an actual reduction to practice of the subject matter of the counts 'reads on' the specific limitations required by each of the counts." *Id.* at 64. Moreover, the Board found that Chen did not produce any evidence establishing

how Chen identified any compounds within the counts in the reaction mixtures he prepared, or even that he ever resolved any such mixtures into their component parts. *Id.*

The record does not indicate how, if at all, the analytical data obtained by the analytical chemists to whom Chen sent his compounds for analysis "confirm" Chen's suggested structures, containing instead only attorney arguments and conclusory proclamations that

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the data are "consistent" with Chen's suggestions. *Id.* at 69. The Board found, in particular, that it cannot be determined from the chemists' conclusions what formed the underlying basis for their belief that the tested samples were "consistent" with the structures proposed by Chen. Indeed, as Bouchard points out, to establish "adequate" identification of the *epi*-route compounds, Chen relies on the same analytical techniques, namely NMR and MS, that resulted, as of July 1, 1992, in a firm (but incorrect) conclusion that a mixture of fluorotaxols had been obtained. As found by the Board, the NMR and MS spectra that Chen apparently relies on to "confirm" the structure of the compounds as compounds within the counts are capable of more than one reasonable interpretation. *Id.* at 75.

Finally, the Board found that "[t]here is neither evidence contemporaneous in time with Dr. Chen's notebook entries nor evidence independent of any of the inventors (Chen and Farina) which corroborates Dr. Chen's testimony concerning the alleged actual reductions to practice." *Id.* at 74. As noted by the Board, no witness who signed any of Dr. Chen's or any other involved researchers' notebooks testified in this proceeding, and all of the information within those notebooks therefore remains uncorroborated. *Id.* at 77.

As to Chen's alternative theory of conception coupled with diligence toward reduction to practice, the Board found "an even greater paucity of detail with respect to the underlying facts." *Id.* at 81. The Board found, in particular, that "[t]he section of Chen et al.'s brief devoted to the 'reasonable diligence' aspect of their priority case is little more than various conclusions made without regard to any underlying facts which support the conclusions made by Chen et al." *Id.* at 82. The Board identified the "critical period" for diligence as running from December 8, 1992 to March 13, 1993, and found that Chen had provided "absolutely no evidence of who worked on what applications on which days for any day in the critical period." *Id.* at 83-84. With regard to compounds BMS-183582 and BMS-183821, the Board found the corresponding data to be unreliable, some having been replotted years later, others having inconsistent dates, some prior to the critical date and others later. *Id.* at 95-97, 99-103. The Board concluded that, while Chen was undoubtedly "actively engaged in synthesizing derivatives of taxol in the critical time period," his proofs do not allow for "identification of exactly what was prepared," and "[c]ompounding this problem is the absence of adequate evidence establishing how Dr. Chen and the other researchers separated the compounds allegedly produced and subsequently tested the compounds for structural determination and utility." *Id.* at 104.

On the basis of these and the numerous other findings of the Board, we hold that substantial evidence supports the Board's conclusion that Chen did not establish by preponderant evidence either that he actually reduced to practice the subject matter of the counts before Bouchard's effective filing date or that he conceived the subject matter of the counts before Bouchard's effective filing date and then was reasonably diligent in constructively or actually reducing the subject matter of the counts to practice in a period beginning just prior to Bouchard's effective filing date. Accordingly, we affirm the Board's decision.

CONCLUSION

Because the Board's decision was supported by substantial evidence and contained no errors of law, the Board did not err in concluding that Chen failed to show (1) entitlement to the benefit of the July 1, 1992 filing date of the '261 application or the January 19, 1993 filing date of the '423 application and/or (2) sufficiently corroborated evidence of conception prior to the December 8, 1992 filing date of Bouchard's French application, followed by diligence from just prior to that date up to an actual or constructive reduction to practice of any compounds within the three counts. Moreover, the Board did not abuse its discretion by excluding hearsay and unauthenticated evidence presented by Chen. The Board's decision to award judgment to Bouchard with respect to all three counts is therefore

AFFIRMED.

Concurring/Dissenting Opinion Text

Concurrence/Dissent By:

Newman, J., dissenting in part.

I agree that Chen is not entitled to the filing date of either the '423 or the '261 application, for these specifications do not name or picture or describe the cyclopropataxol compound of the counts, or recognize that this compound is inherently present. Accepting that the compound is in fact formed by the procedure there

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used, the content of these applications does not establish priority to the counts directed to the cyclopropataxol compounds.

However, the deficiencies of the first two applications are irrelevant to the '819 application, wherein the correctly identified cyclopropataxol compound was made, described, pictured, and claimed. That application is a constructive reduction to practice of the counts. Its filing date, however, is after the effective date of the party Bouchard, requiring Chen to prove conception and either actual reduction to practice or diligence to his filing date. I do not agree that those proofs were not met by a preponderance of evidence.

Chen's conception of the cyclopropataxol of the counts, and the extensive documentary and testimonial evidence of its synthesis, identification, analysis, and biological activity, were presented and documented in a straightforward manner, in accordance with standard laboratory practices and scientific protocols. The Board abused its discretion in refusing to admit the research notebooks of Chen's assistant Jianmei Wei. The Board excluded the notebooks on the basis that they were hearsay and not within the business records exception to the hearsay rule. The Board held, citing Fed. R. Evid. 803(6), that Chen was required to prove that the notebooks were

made at or near the time by, or from information transmitted by, a person with knowledge, if kept in the course of regularly conducted business activity, and if it was the regular practice of that business activity to make the memorandum, report, record or data compilation, all as shown by *the testimony of the custodian or other qualified witness*, unless the source of information or the method or circumstances of preparation indicate lack of trustworthiness.

Board Op. at 52 (emphasis by the Board). There can be no dispute that Chen satisfies the criteria of a "qualified witness," under Rule 803(6), or that it was the regular practice to keep research notebooks. See *Air Land Forwarders, Inc. v. United States*, 172 F.3d 1338, 1344 (Fed. Cir. 1999) (where additional guarantees of reliability were present, the business records "were properly admitted by the trial court even though the government did not produce a witness that could testify with first-hand knowledge as to the procedures used in the original preparation of each of the repair estimates"); *Conoco v. Department of Energy*, 99 F.3d 387, 391 (Fed. Cir. 1996) ("Courts have made clear, however, that the 'custodian or other qualified witness' who must authenticate business records need not be the person who prepared or maintained the records, or even an employee of the record-keeping entity, as long as the witness understands the system used to prepare the records."). Chen testified that the notebooks were those of Ms. Wei, that he supervised her work and reviewed the notebooks, and that the information sought to be admitted was timely recorded. The Board erred in refusing to consider Chen's testimony on the ground that it was not corroborated. Not every aspect of an inventor's testimony requires corroboration.

As authority, the Board cited *Holmwood v. Sugavanam*, 948 F.2d 1236 (Fed. Cir. 1991). But *Holmwood* does not stand for the proposition that an inventor's testimony as to the authenticity of a business document must be corroborated. I can find no case that holds an inventor's testimony must be corroborated as to such routine matters as the maintenance of business records, nor does the panel majority cite to one. See *id.* at 1239 ("only an inventor's testimony needs corroboration"); *Conoco*, 99 F.3d at 391 ("Because of the general trustworthiness of regularly kept records and the need for such evidence in many cases, the business records exception has been construed generously in favor of admissibility.") The panel majority ignores this precedent, requiring that the operator of the research laboratory provide evidence of its policies concerning research notebooks. Indeed, one can always dream up testimony that might have been provided, had the PTO required it. The issue, however, is the sufficiency of what was actually provided.

The requirement that inventor testimony be corroborated arose from recognition of a combination of human frailty and faltering memory, exacerbated by the high stakes of the priority contest. These concerns apply to the acts that are presented to prove conception and reduction to practice. They do

not apply to such routine matters as whether notebooks are kept, and to require corroboration of everything to which an inventor testifies, simply because he is an inventor, amounts to the establishment of a rebuttable presumption of dishonesty. See *Kridl v. McCormick*, 105 F.3d 1446, 1451 (Fed. Cir. 1997) ("While there must generally be corroboration of an inventor's

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testimony of conception of his or her invention, the utility of the invention need not always be explicitly corroborated."). See also *Ethicon, Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 1464 (Fed. Cir. 1998) ("Accordingly, there need not be corroboration for every factual issue contested by the parties."). We should not ratify the Board's erroneous application of the rules of evidence and of precedent.

Bouchard's motion to suppress the Wei notebooks was filed in August, 2000, almost four years after the deadline of November 13, 1996 that the APJ had set for filing such motions. Chen points out that permitting this tardy objection, after the record had closed, prevented him from presenting additional evidence of the notebooks' authenticity. In failing to apply its own rules, the Board committed seriously prejudicial error.

There was no evidence whatsoever that the notebooks were not those of Ms. Wei, or that they were inaccurate or falsified or in any way unreliable. The Board has simply imposed a new evidentiary rule upon inventors and done it in a way that is manifestly unfair. Ms. Wei's notebooks were business records, and were qualified for admission into evidence; it is not necessary that the "custodian" of business records testify when the records are credibly and reasonably authenticated. Further, a motion to suppress such evidence as unauthenticated must be timely made, not withheld until after the evidentiary record has closed and it is too late to remedy any technical flaw.

The persons who performed the many analyses reasonably, and correctly, confirmed the proposed structure. The Board departed from its own rules of interference evidence in requiring corroboration of the testimony of the non-inventor analytical scientists. Further, confirmation of the structure of this complex molecule by the analysts need not exclude knowledge of the inventor's proposed structure, and I agree with the panel majority that the Board's requirements exceeded accepted and reasonable scientific procedure.

When the evidence presented to the Board is properly admitted and considered, Chen easily established conception and actual reduction to practice before the effective filing date of the party Bouchard. From the court's contrary holding, I respectfully dissent.

- End of Case -

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